BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

UNITED STATES PATENT AND TRADEMARK OFFICE

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| APPLICANTS | : | Kieran Murphy |
| APPLICATION NO. | : | 10/727,667 |
| TITLE | : | DEVICE VIEWABLE UNDER AN IMAGING BEAM |
| FILING DATE | : | December 5, 2003 |
| EXAMINER | : | BUI, VY Q. |
| GROUP ART UNIT | : | 3773 |
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**APPEAL BRIEF**

United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Honorable Board:

This Appeal Brief is further to the Notice of Appeal filed August 25, 2009, and in support of the appeal from the final rejection set forth in the Office Action mailed on May 29, 2009. The fee for filing a brief in support of an appeal is enclosed.

## Table of Contents

**Real Party in Interest**: The name of the real party in interest is Kieran Murphy LLC.

**Related Appeals and Interferences**:

There are no related appeals or interferences.

**Status of Claims**:

Claims 1, 4 and 10-16 (Rejected)

Claims 2, 3, 5-9 and 17-23 (Withdrawn)

**Status of Amendments:**

No amendments have been made to the claims subsequent to the final rejection of May 29, 2009.

**Summary of Claimed Subject Matter:**

A stent[1] is set forth, according to an embodiment. The stent comprises a material having structure to provide three-dimensional visualization of a surrounding tissue when the stent is inserted into the tissue and viewed under an imaging beam[2]. The stent has a coating[3] selected from a group consisting of: a hydrophilic polymer[4], a hydrophobic polymer[5], and a fatty acid polymer[6]. The stent also has a density enhancing radiologic opacifier embedded into the polymer[7], the coating and the embedded opacifier material together providing a first Hounsfield image density suitable for viewing under a first image modality used during device insertion into a patient, and wherein the density enhancing radiologic opacifier material is configured to elute from the coating so as to provide a second Hounsfield image density suitable for viewing under a second image modality used for subsequent visualization of surrounding tissue[8].

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1 Reference 150 in paragraphs [0055], [0058]-[0059], [0065] and Figure 6

2 Paragraphs [0055], [0058]-[0059]

3 Paragraph [0067]

4 Paragraph [0068]

5 Paragraph [0020]

6 Paragraph [0020]

7 Paragraph [0068]

8 Paragraph [0068]

A polymer[1] is set forth, according to an embodiment, for coating a medical device[2] for temporarily increasing the radiological opacity of the medical device for x-ray examination. The polymer comprises a therapeutically effective amount of a drug; a density increasing radiologic opacifier material. The polymer is formulated to promote elution of the drug and the density increasing radiologic opacifier material from the medical device over time[3]. Residual density measurements of the medical device provide a measure of the drug still retained within the polymer.

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1 Paragraphs [0067]-[0068]

2 Reference 150 in paragraphs [0055], [0058]-[0059], [0065] and Figure 6

3 Paragraphs [0067]-[0068]

**Grounds of Rejection to be Reviewed on Appeal:**

Claims 1, 4 and 10-16 stand rejected under 35 U.S.C. 102(b) as anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,609,629 (Fearnot, et al., hereinafter "Fearnot").

**Arguments:**

**Rejection of claims 1, 4 and 10-16 in the alternative**

At page 2 of the final rejection of May 29, 2009, claims 1, 4 and 11-16 are rejected "under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fearnot." Applicant first notes that in the final rejection, claim 10 was indicated as having been withdrawn from consideration. However, claim 10 was not in fact withdrawn. Applicant has therefore assumed that the Examiner intended to reject claim 10 along with claims 1, 4 and 11-16.

With regards to the rejection of the claims "in the alternative," Applicant submits that such a rejection fails to clearly specify which legal test is being applied to the claims. The MPEP, at section 706.02, reads in part as follows:

> "By far the most frequent ground of rejection is on the ground of unpatentability in view of the prior art, that is, that the claimed subject matter is either not novel under 35 U.S.C. 102, or else it is obvious under 35 U.S.C. 103. The language to be used in rejecting claims should be unequivocal." *[emphasis added]*

> "The distinction between rejections based on 35 U.S.C. 102 and those based on 35 U.S.C. 103 should be kept in mind. Under the former, the claim is anticipated by the reference. No question of obviousness is present. In other words, for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. Whereas, in a rejection based on 35 U.S.C. 103, the reference teachings must somehow be modified in order to meet the claims. The modification must be one which would have been obvious to one of ordinary skill in the art at the time the invention was made." *[emphasis added]*

The Examiner has therefore asserted that Fearnot simultaneously anticipates the claims (in which case no modification of Fearnot would be necessary) and renders the claims obvious following some necessary, but unspecified, modification. These two possibilities cannot coexist, and thus by rejecting the claims for either anticipation or obviousness, the Examiner has failed to use "unequivocal" language in order to clearly set out the grounds of rejection.

Applicant further submits that, for reasons to be laid out in detail below, the Examiner has additionally failed to satisfy the requirements for either one of a rejection based on anticipation and a rejection based on obviousness.

**Rejection of claims 1, 4 and 10-16 under 35 U.S.C. 102(b)**

Claims 1, 4 and 10-16 stand rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,609,629 (Fearnot).

Claim 1

In order to support a finding of anticipation the Examiner must show that Fearnot teaches each and every element of the claims:

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)" *[emphasis added]*

As argued in Applicant's Pre-Appeal Brief Request for Review of August 25, 2009, Fearnot fails to satisfy each and every element of Applicant's claim 1, and therefore cannot anticipate claim 1. In particular, Fearnot fails to satisfy at least the following element of claim 1:

"a density enhancing radiologic opacifier embedded into said polymer"

At column 6, line 51 Fearnot describes a device with a "structure 12 composed of a base material 14." Such a device is shown, for example, in Fearnot's Figure 1. Fearnot also recites, at column 7, lines 30-32, "at least one layer of a bioactive material positioned over the structure." Still further, Fearnot recites, at column 9, lines 27-29, "at least one porous layer 20 positioned over the layer 18 of bioactive material." As noted by the Examiner, Fearnot's bioactive material can be an iodine-containing compound. However, Fearnot makes no mention whatsoever of "a density enhancing radiologic opacifier material embedded into said polymer" *[emphasis added]*. Indeed, Fearnot does not provide any material embedded into any other material. Rather, as can be clearly seen in each and every one of Fearnot's drawings and as evidenced at least by the above-cited passages of Fearnot, the various materials layered over Fearnot's device 14 are disposed in discrete layers. An arrangment in such discrete layers is mutually exclusive with an embedded arrangement as recited in Applicant's claim 1.

Further support for Applicant's position can be found at column 13, lines 15-22 of Fearnot, where the method of making Fearnot's device is described. In particular, Fearnot provides "positioning the at least one layer 18 of bioactive material over the structure 12, and positioning the at least one porous layer 20 by vapor deposition or plasma deposition over the at least one bioactive material layer 18." The different materials are thus clearly placed separately from each other and one on top of the other, precluding any possibility of embedding either material into the other.

Claim 1 thus cannot possibly be anticipated by Fearnot, and is patentable for at

least the above reasons. The rejection of claim 1 should therefore be withdrawn.

Claims 4 and 10-16

Claims 4 and 10-16 depend on claim 1. Fearnot cannot satisfy each and every element of any of claims 4 and 10-16 for at least the reasons set out above in connection with claim 1. Claims 4 and 10-16 are therefore patentable for at least the above reasons, and the rejection of claims 4 and 10-16 should be withdrawn.

**Rejection of claims 1, 4 and 10-16 under 35 U.S.C. 103(a)**

Claims 1, 4 and 10-16 stand rejected under 35 U.S.C. 103(a) as being obvious in view of U.S. Patent No. 5,609,629 (Fearnot).

Claim 1

In order to support a finding of obviousness the Examiner must show that the cited art teaches or suggests each and every limitation of the rejected claim:

> When determining whether a claim is obvious, an examiner must make "a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974))."

*Ex Parte Wada and Murphy*, Appeal No. 2007-3733, Bd. Pat. App. & Inter., January 14, 2008. The Examiner must also provide "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" (*KSR International Co. v. Teleflex Inc.* (KSR), 550 U.S., 82 USPQ2d 1385 (2007)). Because at least one limitation of claim 1 is not satisfied by Fearnot and because the

Examiner has failed to provide the requisite reasoning, an obviousness rejection would be improper.

Specifically, as discussed above Fearnot does not satisfy at least the element of, "a density enhancing radiologic opacifier embedded into said polymer," recited in Applicant's claim 1. The Examiner has provided no indication of where in Fearnot such an element is provided. The Examiner has also not asserted any other teaching of the element, or provided any other reasoning as to how a person skilled in the art would come to apply the element to Fearnot. Applicant further submits that by explicitly teaching that separate materials are to be placed in separate layers, Fearnot would in fact lead a person skilled in the art directly away from such an element, even if the element were to be found elsewhere in the prior art. For instance, at column 9, lines 53-59, Fearnot states:

> "It is for this reason that the bioactive material lies under the at least one porous layer 20, rather than being dispersed within or throughout it." *[emphasis added]*

Fearnot thus explicitly discourages the very element recited in Applicant's claim 1, and would lead a person skilled in the art away from embedding any material into any other material. Claim 1 thus cannot be obvious in view of Fearnot, and is patentable for at least the above reasons. The rejection of claim 1 should therefore be withdrawn.

Claims 4 and 10-16

Claims 4 and 10-16 depend on claim 1. Fearnot cannot satisfy each and every element of any of claims 4 and 10-16 for at least the reasons set out above in connection with claim 1. Claims 4 and 10-16 are therefore patentable for at least the above reasons, and the rejection of claims 4 and 10-16 should be

withdrawn.

Applicant therefore respectfully requests that the Honorable Board issues a decision overturning the final rejection and remands this application to the Examiner for issuance of a Notice of Allowance and a Notice of Allowability consistent with such decision.

Respectfully submitted,

Frank Chau
Reg. No. 34,136

11/30/09
(date)

**Claims Appendix:**

1. (Rejected) A stent, comprising:

a material having structure to provide three-dimensional visualization of a surrounding tissue when said stent is inserted into said tissue and viewed under an imaging beam,

said stent having (i) a coating selected from a group consisting of: (i)(a) a hydrophilic polymer, (i)(b) a hydrophobic polymer, and (i)(c) a fatty acid polymer, and (ii) a density enhancing radiologic opacifier embedded into said polymer,

said coating and said embedded opacifier material together providing a first Hounsfield image density suitable for viewing under a first image modality used during device insertion into a patient, and wherein said density enhancing radiologic opacifier material is configured to elute from said coating so as to provide a second Hounsfield image density suitable for viewing under a second image modality used for subsequent visualization of surrounding tissue.

2. (Withdrawn) The stent according to claim 1 wherein said coating includes a restenosis inhibiting drug.

3. (Withdrawn) The stent according to claim 1, wherein said density enhancing radiologic opacifier material comprises a dehydrated nonionic contrast.

4. (Rejected) The stent according to claim 1, wherein said density enhancing radiologic opacifier material comprises a lyophilizied iodinated contrast.

5. (Withdrawn) The stent according to claim 1, wherein said density enhancing radiologic opacifier material comprises a tungsten, tantalum, or barium contrast.

6. (Withdrawn) The stent according to claim 1, wherein said density enhancing

radiologic opacifier material comprises a gadolinium based contrast.

7. (Withdrawn) The stent according to claim 1, wherein said density enhancing radiologic opacifier material comprises a lipidol or ethiodol based contrast.

8. (Withdrawn) The stent according to claim 1, wherein said density enhancing radiologic opacifier material is selected from the group consisting of inconel and metal glass.

9. (Withdrawn) The stent according to claim 1, wherein said density enhancing radiologic opacifier material is selected from the group consisting of nitinol and stainless steel.

10. (Rejected) The stent according to claim 1, wherein said density enhancing radiologic opacifier material is selected from the group consisting of a robust plastic and a polymeric formulation.

11. (Rejected) The stent of claim 1, wherein said stent is configured to elute said density enhancing radiologic opacifier material by bulk erosion, such that said stent has increased visibility than said stent prior to elution.

12. (Rejected) The stent of claim 1, wherein said stent is configured to elute said density enhancing radiologic opacifier material by surface erosion, such that said stent has increased visibility when viewed under an imaging beam than said stent prior to elution.

13. (Rejected) The stent of claim 1, wherein said stent is configured to elute said density enhancing radiologic opacifier material by diffusion, such that said stent has increased visibility when viewed under an imaging beam than said stent

prior to elution.

14. (Rejected) The stent of claim 1, wherein said stent is configured to elute said density enhancing radiologic opacifier material by degradation, such that said stent has increased visibility when viewed under an imaging beam than said stent prior to elution.

15. (Rejected) The stent of Claim 11, wherein said imaging comprises CT.

16. (Rejected) The stent of Claim 11, wherein said imaging comprises MR.

17. (Withdrawn) The stent of Claim 11, wherein said stent further includes a restenosis inhibiting drug.

18. (Withdrawn) The stent of claim 2, wherein residual radiographic density measurements of said stent provide a measure of said restenosis inhibiting drug still retained within said polymer.

19. (Withdrawn) A polymer for coating a medical device for temporarily increasing the radiological opacity of the medical device for x-ray examination, said polymer comprising:

a therapeutically effective amount of a drug;

a density increasing radiologic opacifier material;

wherein said polymer is formulated to promote elution of said drug and said density increasing radiologic opacifier material from said medical device over time, and

wherein residual density measurements of said medical device provide a measure of said drug still retained within said polymer.

20. (Withdrawn) The polymer of claim 19, wherein the polymer is selected from the group consisting of a hydrophilic polymer, a hydrophobic polymer, and a fatty acid polymer.

21. (Withdrawn) The polymer of claim 19, wherein the drug comprises a restenosis inhibiting drug.

22. (Withdrawn) The polymer of claim 19, wherein the density increasing radiologic opacifier material is selected from the group consisting of: gold, iodine, ionic and non-ionic iodinated compounds, ethiodol, lipiodol, barium, tungsten, tantalum, and gadolinium.

23. (Withdrawn) The polymer of claim 19, wherein the density increasing radiologic opacifier material comprises a lyophilized iodinated contrast material.

**Evidence Appendix:**

No additional evidence is to be relied upon in the appeal.

**Related Proceedings Appendix:**

There are no related appeals or interferences.